UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

DERRICK C. BOSLEY, SR.,

Plaintiff,

v.

DePUY SYNTHES SALES INC., *et al.*,

Defendants.

Case No. C21-1683-MLP

ORDER

I. INTRODUCTION

This matter is before the Court on: (1) Defendants' Motion to Exclude the Report and Opinions of Plaintiff's Expert Dr. Peter Bonutti ("Daubert Motion" (dkt. # 65)); and (2) Defendants' Motion for Summary Judgment ("Summary Judgment Motion" (dkt. # 73)). Plaintiff Derrick C. Bosley, Sr., has filed oppositions to both motions (Daubert Resp. (dkt. # 78); Summ. J. Resp. (dkt. # 84)), and Defendants have filed replies (Daubert Reply (dkt. # 80); Summ. J. Reply (dkt. # 85)). The Court held oral argument on August 28, 2023. (Dkt. # 87.) Having considered the parties' submissions, oral argument, the governing law, and the balance of the record, the Court DENIES Defendants' Daubert Motion (dkt. # 65) and DENIES Defendants' Summary Judgment Motion (dkt. # 73).

II. BACKGROUND

Mr. Bosley alleges that Defendants defectively designed, manufactured, and/or sold without proper warning, the DePuy Attune Knee System ("Attune Device"). (*See* Second Am. Compl. (dkt. # 37) at ¶ 1.) In August 2014, Mr. Bosley's surgeon, William Barrett, M.D., performed a total knee arthroplasty and implanted the Attune Device in Mr. Bosley's left leg. (Daubert Resp. at 5, Ex. 2 (Barrett Dep. (dkt. # 78-2) at 86).)

Mr. Bosley alleges that, due to its defective design and/or construction, the Attune Device loosened and failed after implant as a result of "debonding at the interface between the baseplate and the cement which was supposed to adhere to and hold the baseplate." (Second Am. Compl. at ¶¶ 1-2.) As a result of the implant's failure, Mr. Bosley was required to undergo revision surgery in March 2019, replacing the Attune Device with a new knee implant. (*Id.* at ¶ 5.)

On January 23, 2019, Dr. Barrett's physician assistant, Jana Flener, PA-C, stated in a treatment note that X-ray images showed "the bone cement interfaces are intact at the . . . tibia[.]" (Daubert Resp. at 7 n.9, Ex. 5.) She wrote: "Impression: Potential loosening of the left total knee arthroplasty." (*Id.*) On March 19, 2019, Dr. Barrett, assisted by Ms. Flener, performed the revision surgery and implanted a new device. (First Pauley Decl. (dkt. # 66) at ¶ 5, Ex. C (dkt. # 66-3).)

In support of his allegations of defective design, Mr. Bosley submitted the expert report of Peter M. Bonutti, M.D. (*See* First Pauley Decl. at ¶ 3, Ex. A (dkt. # 66-1).) Relevant to the instant motions, Dr. Bonutti reviewed Ms. Flener's January 2019 treatment note and Dr. Barrett's March 2019 operative report. (*Id.* at 4-5.) Dr. Bonutti concluded that Mr. Bosley's Attune Device "separated at the implant/cement interface which is consistent with debonding of the tibial implant." (*Id.* at 4.)

Dr. Bonutti also opined that certain features of the Attune Device made debonding more likely. Specifically, the "rougher surface and undercut pockets" of Defendants' previous "Sigma" device were "skipped" in the Attune Device but then "re-adapted" in the next generation "Attune S+" device. (First Pauley Decl., Ex. A at 7-8.) Dr. Bonutti opined that "[i]t appears this design change was made to address the problem of tibial debonding and potential insufficient cement fixation" in the Attune Device. (*Id.* at 8.)

III. DISCUSSION

A. Daubert Motion

Defendants seek to exclude Dr. Bonutti's opinions that: (1) Mr. Bosley's Attune Device debonded at the implant/cement interface, causing implant failure; and (2) that the surface roughness and lack of undercut pockets were design defects that made debonding more likely. (First Pauley Decl., Ex. A at 4, 8; Daubert Mot.) Defendants argue that the probative value of Dr. Bonutti's opinions is substantially outweighed by the danger of unfair prejudice, confusion of the issues, and misleading the jury because his opinions are directly contradicted by Dr. Barrett's deposition testimony. (Daubert Mot. at 7.)

Mr. Bosley contends Dr. Bonutti's opinions are based on his interpretation of Dr. Barrett's and Ms. Flener's records, just as Dr. Barrett's opinions must be because Dr. Barrett testified that he did not remember Mr. Bosley's surgery and was relying on the same records. (Daubert Resp. at 4.) Accordingly, Mr. Bosley contends, it is the province of the factfinder to weigh Dr. Bonutti's and Dr. Barrett's opinions. (*Id.* at 13.)

1. Legal Standards

Federal Rule of Evidence 702 provides in relevant part:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's

> scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. For expert testimony to be admissible under Rule 702, it must satisfy three requirements: (1) the expert witness must be qualified; (2) the testimony must be reliable; and (3) the testimony must be relevant. *See Daubert v. Merrell Dow Pharms., Inc.* ("*Daubert I*"), 509 U.S. 579, 589-91 (1993). The proponent of expert testimony has the burden of establishing that the admissibility requirements are met by a preponderance of the evidence. *Id.* at 592 n.10; *see also Lust v. Merrell Dow Pharms., Inc.*, 89 F.3d 594, 598 (9th Cir. 1996).

Before admitting expert testimony into evidence, the Court acts as a "gatekeeper" in determining its admissibility under Rule 702 by ensuring the testimony is both "relevant" and "reliable." *United States v. Ruvalcaba-Garcia*, 923 F.3d 1183, 1188 (9th Cir. 2019) (citing *Daubert I*, 509 U.S. at 597). Expert testimony is relevant where "the evidence logically advance[s] a material aspect of the party's case." *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463 (9th Cir. 2014) (internal quotations and citation omitted), *overruled on other grounds by United States v. Bacon*, 979 F.3d 766 (9th Cir. 2020) (en banc). Testimony is reliable where it has "a reliable basis in the knowledge and experience of the relevant discipline." *Id.* (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999)).

The Supreme Court has noted the reliability inquiry is a "flexible one," and while the Supreme Court has suggested several factors helpful in determining reliability, trial courts are generally given "broad latitude in determining the appropriate form of the inquiry."[1] *United*

[1] In relevant part, *Daubert I* suggested several reliability factors a trial court may examine to determine the reliability of expert testimony, including: (1) whether a theory or technique can be tested; (2) whether it has been subjected to peer review and publication; (3) the known or potential error rate of the theory or

States v. Wells, 879 F.3d 900, 934 (9th Cir. 2018) (quoting *Kumho Tire*, 526 U.S. at 150); *see also Messick v. Novartis Pharm. Corp.*, 747 F.3d 1193, 1196 (9th Cir. 2014) (finding Rule 702 should be applied with a "liberal thrust" favoring admission) (quoting *Daubert I*, 509 U.S. at 588); *United States v. Hankey*, 203 F.3d 1160 (9th Cir. 2000) (Rule 702 is "construed liberally" in considering admissibility of testimony based on specialized knowledge).

Furthermore, the reliability inquiry favors admission of testimony as "[s]haky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion." *Primiano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010) (citing *Daubert I*, 509 U.S. at 596). The reliability inquiry test does not seek to measure "the correctness of the expert's conclusions but the soundness of [his or her] methodology," and therefore, when an expert meets the standards established by Rule 702, "the expert may testify[,] and the fact finder decides how much weight to give that testimony." *Pyramid Techs., Inc. v. Hartford Cas. Ins. Co.*, 752 F.3d 807, 814 (9th Cir. 2014) (quoting *Primiano*, 598 F.3d at 564-65).

2. Dr. Bonutti's Causation Opinion

There is no dispute that Dr. Bonutti is an orthopedic surgeon who is highly qualified to interpret the operative reports of other orthopedic surgeons, such as Dr. Barrett. (*See* Daubert Resp. at 3, Ex. 1 (dkt. # 78-1); Daubert Reply at 4.) Dr. Barrett's operative report states:

> Using an oscillating saw and osteotomes, we removed the femoral component, which was not loose, without complication. We then turned ou[r] attention to the tibia. There was loosening of the implant with medial subsidence. We removed the scar tissue around the tibia and knocked the tibial component out of the cement mantle. We then removed the cement in a sequential fashion.

(First Pauley Decl., Ex. C at 2.)

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technique; (4) the existence and maintenance of standards and controls; and (5) whether the theory or technique enjoys general acceptance within the relevant scientific community. *Daubert I*, 509 U.S. at 592-94; *see also Mukhtar v. California State Univ., Hayward*, 299 F.3d 1053, 1064 (9th Cir. 2002).

During a deposition in April 2023, Dr. Barrett stated that he "do[es]n't specifically remember this case, so [he has] to refer to what [he] put in [his] operative report." (First Pauley Decl. at ¶ 4, Ex. B (Barrett Dep. (dkt. # 66-2) at 10:25-11:2).) Based on his review of his report, Dr. Barrett stated:

> I have done many knee revisions in my career, and if an implant is debonded, either on the femoral side or the tibial side – and it can – you can have debonding of the implant cement from the bone itself, or you can have debonding of the implant from the cement and the cement is still intact in the bone. And I'll state that. I'll say it came off with finger pressure. I'd literally pull it off.
>
> So if an implant is debonded, it will just pop right off. And in my notes, I talk about having to work and remove the implant. I mean, it's loose, so it came out, but to the best of my recollection, based on reading my notes, it didn't just pop out of the cement interface.

(*Id.* at 12:14-13:2.) Dr. Barrett opined that, "to the best of [his] knowledge, [Mr. Bosley] did not have clearcut debonding of the tibial component from the tibial cement." (*Id.* at 14:9-11.)

Defendants first argue that Dr. Bonutti's opinion that debonding occurred is not based on adequate facts because "[n]o evidence exists of any 'debonding' of the tibial baseplate from the cement[.]" (Daubert Mot. at 6.) Testimony may be excluded under Rule 702(d) where there is "too great an analytical gap between the data and the opinion proffered" to support inclusion of the testimony. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); Fed. R. Evid. 702 Advisory Committee's Note to 2000 Amendments (noting relevant factors include "[w]hether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion"). An expert must therefore bridge the analytic gap with more than bald assertions. *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1049 (9th Cir. 2014) ("It is where expert opinion is 'connected to the existing data only by the *ipse dixit* of the expert' that there may be 'too great an analytical gap between the data and the opinion proffered' to support inclusion of the testimony.") (internal citation and quotations omitted); *see also Provident Life & Accident Ins. Co. v. Fleischer*, 18 F.

App'x 554, 556 (9th Cir. 2001) (excluding expert's testimony where report "did little more than baldly state" a conclusion, "offer[ed] absolutely no foundation for the conclusion," and did "not explain what, if any, scientific studies or principles support[ed] that conclusion.").

However, pursuant to Rule 702(b), the requirement that expert testimony be based on "sufficient facts or data" only requires the Court to engage in "an analysis of the sufficiency of underlying facts or data that is quantitative rather than qualitative." *United States v. W.R. Grace*, 455 F. Supp. 2d 1148, 1152 (D. Mont. 2006); *see also* Fed. R. Evid. 702 Advisory Committee's Note to 2000 Amendments. The requirement "is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other." *W.R. Grace*, 455 F. Supp. 2d at 1152.

Here, Dr. Bonutti cites adequate data to support his opinion that debonding occurred. Dr. Bonutti relies on Ms. Flener's treatment notes and Dr. Barrett's operative report. Dr. Barrett's opinions necessarily rely on the same evidence, as he concedes he does not have any personal recollection of the surgery.[2] Dr. Bonutti is permitted to rely on the same facts that Dr. Barrett does. This Court may not exclude one expert or the other by selecting which version of the facts to believe. Essentially, Defendants ask the Court to accept Dr. Barrett's interpretation of his operative report as definitive because he was its author. While his authorship may be relevant to the jury's credibility determination, the Court cannot, as a matter of law, determine that Dr. Barrett's interpretation is the only correct one.

Defendants also argue that "the records do *not* state that the tibial component of Plaintiff's Attune implant 'debonded' or otherwise failed to adhere at the cement-implant

[2] Dr. Barrett acknowledged during his deposition that his opinion is an "assumption" rather than a fact. (First Pauley Decl., Ex. B (Barrett Dep. at 15:24-16:1) ("So my assumption, based on the x-rays, and what I wrote in my note is that the cement had failed between the implant and the bone[.]").)

interface." (Daubert Reply at 4.) The records, however, likewise do not state that the implant debonded or otherwise failed to adhere at the cement-bone interface, as Dr. Barrett opines in his deposition. The jury will require experts such as Dr. Bonutti and Dr. Barrett to interpret the medical records on this issue. Dr. Bonutti should not be excluded based on a lack of factual foundation.

Next, Defendants argue that Dr. Bonutti did not reliably apply a methodology because, in a journal article he co-authored about Attune Device debonding, "Dr. Bonutti observes . . . debonding of the tibial component from cement is best identified at revision surgery under direct observation by the operating surgeon, rather than from pre-operative radiographic findings." (Daubert Mot. at 4 (citing Peter M. Bonutti, *et al.*, *Unusually High Rate of Early Failure of Tibial Component in ATTUNE Total Knee Arthroplasty System at Implant-Cement Interface*, 30 J. Knee Surg. 435-39, 437-38 (2017) ("Bonutti Article")).) Defendants' argument is not supported by the record. While the Bonutti Article does note that "most of the patients had negative findings on radiographic evaluation, which can be attributed to the unusual mechanism of failure through debonding of the implant-cement interface[,]" it does not state that debonding is best observed by the revising surgeon. Bonutti Article at 438. The Bonutti Article relies on interpreting other surgeons' operative reports. *Id.* at 436 ("Data Collection: . . . Intraoperative findings were obtained from surgical notes."). This is not a reason why Dr. Bonutti's opinions should be excluded as based on interpreting another surgeon's operative report.

The methodology that both Dr. Bonutti and Dr. Barrett used essentially amounts to applying their knowledge and experience as orthopedic surgeons to interpret orthopedic surgery operative reports and other treatment notes. Defendants' attempt to insert another step in this

methodology—to require that only the operating surgeon can identify debonding—is not supported by the record.

Finally, Defendants argue Dr. Bonutti's opinions should be excluded because he failed to consider "alternative causes of the loosening" such as "obesity and chronic narcotic use[.]" (Daubert Mot. at 12.) While the relative contribution of such factors to the failure of the Attune Device may be relevant to the factfinder's determination, these issues go to the weight, not the admissibility, of Dr. Bonutti's opinion. *See Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1231 (9th Cir. 1998) ("Disputes as to the strength of [an expert's] credentials, faults in his use of [a particular] methodology, or lack of textual authority for his opinion, go to the weight, not the admissibility, of his testimony.") (alterations in original) (quoting *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995)). Defendants may make such challenges in the course of Dr. Bonutti's cross-examination.

Defendants' arguments that Dr. Bonutti's causation opinion is unreliable fail. Accordingly, the Court denies Defendants' Daubert Motion as to Dr. Bonutti's causation opinion.

3. Dr. Bonutti's Design Defect Opinion

Defendants contend Dr. Bonutti's design defect opinion should be excluded because it is based only on his published report of 15 cases of debonding, which they assert was "subsequently discredited." (Daubert Mot. at 11 (citing Bonutti Article).) Defendants provide no support for this assertion. Defendants cite a letter by Michael A. Mont responding to the Bonutti Article. (Daubert Mot. at 4; Daubert Reply at 3 n.1.) Dr. Mont did not discredit the Bonutti Article but noted that, because the total number of Attune Devices implanted was unknown, it was unclear whether debonding was rare or not. *Isolated Group of Failures without*

Denominator, 31 J. Knee Surg. 591-92 (2018). Dr. Mont advocated for a comprehensive implant registry and closed by stating he "would like to think that [the Bonutti Article reflects] only an isolated group of failures that can occur with any device in the field from any manufacturer." *Id.*

Moreover, Dr. Bonutti cited other published research to further support his design defect opinion. In support of his opinion that "tibial debonding . . . may be related to a component of the ATTUNE tibial design[,]" Dr. Bonutti cited *Tibial Baseplate-Cement Interface Debonding in the ATTUNE Total Knee Arthroplasty System* by Daniel Torino, M.D., *et al.* ("Torino Article"). (*See* First Pauley Decl., Ex. A at 6 (citing Torino Article, Arthroplasty Today 17 (2022) 165-71).) In the Torino Article, the authors reviewed all knee replacements using the Attune Device at a large integrated health system and determined that: "*All* cases of aseptic loosening demonstrated debonding at the tibial implant-cement interface[.]" Torino Article at 167 (emphasis added). The authors concluded that "cement debonding is a potential issue with the original [Attune Device] design" and noted that its successor, Attune S+, included "undercut" pockets and increased surface roughness, which "appears to have resolved these issues[.]" *Id.* at 169. Defendants' arguments that Dr. Bonutti's design defect opinion is unsupported fail. Accordingly, the Court denies Defendants' Daubert Motion as to Dr. Bonutti's design defect opinion.

B. Summary Judgment Motion

On reply, Defendants contend that Mr. Bosley failed to address their arguments for dismissal of the following claims: unsafe construction (Count II), breach of express and implied warranty (Counts III and IV), common law negligence and negligent misrepresentation (Counts VI and VII), and Washington Consumer Protection Act violations (Count VIII). (Summ. J. Reply

at 1.) The Court agrees that Mr. Bosley has abandoned these claims, and thus will address below the remaining claims: design defect (Count I) and failure to warn (Count V).

Defendants contend Mr. Bosley's failure to warn and design defect claims must be dismissed pursuant to Restatement (Second) of Torts § 402A, comment k, because the Attune Device package insert warning was adequate as a matter of law and design defect claims are prohibited for prescription devices.[3] (Summ. J. Mot. at 2-3.) Defendants further contend both claims are time-barred. (*Id.* at 3.) Defendants also argue the failure to warn claim must be dismissed because Dr. Barrett, as a learned intermediary, knew of the alleged risks, did not read or rely on the package insert warning, and would not have changed his decision to implant the Attune Device based on different warnings. (*Id.* at 2-3.)

Mr. Bosley contends genuine issues of material fact remain regarding: (1) whether the Attune Device package insert warnings addressed debonding of the implant from the cement; (2) Dr. Barrett's credibility and whether he served as a learned intermediary, based on conflict of interest and that he discarded the Attune Device after revision surgery; and (3) whether Defendants owed a separate duty to warn the medical center that purchased the Attune Device to implant in Mr. Bosley. (Summ. J. Resp.)

1. Summary Judgment Standards

Summary judgment is appropriate when the "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). The moving party is entitled to judgment as a matter of law when the nonmoving party fails to make a sufficient

[3] Defendants also argue the design defect claim must be dismissed because Mr. Bosley cannot offer reliable expert testimony that the Attune Device was defectively designed or that the defect caused his implant failure. (Summ. J. Mot. at 3.) Because the Court denies Defendants' Daubert Motion, these arguments fail.

showing on an essential element of his case with respect to which he has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The moving party bears the initial burden of showing the Court "that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325. The moving party can carry its initial burden by producing affirmative evidence that negates an essential element of the nonmovant's case or by establishing that the nonmovant lacks the quantum of evidence needed to satisfy its burden at trial. *Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Cos., Inc.*, 210 F.3d 1099, 1102 (9th Cir. 2000). The burden then shifts to the nonmoving party to establish a genuine issue of material fact. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The Court must draw all reasonable inferences in favor of the nonmoving party. *Id.* at 585-87.

Genuine disputes are those for which the evidence is such that a "reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 257. It is the nonmoving party's responsibility to "identify with reasonable particularity the evidence that precludes summary judgment." *Keenan v. Allan*, 91 F.3d 1275, 1279 (9th Cir. 1996) (quoted source omitted). The Court need not "scour the record in search of a genuine issue of triable fact." *Id.* (quoted source omitted); *see also* Fed. R. Civ. P. 56(c)(3) ("The court need consider only the cited materials, but it may consider other materials in the record."). Nor can the nonmoving party "defeat summary judgment with allegations in the complaint, or with unsupported conjecture or conclusory statements." *Hernandez v. Spacelabs Med. Inc.*, 343 F.3d 1107, 1112 (9th Cir. 2003); *see McElyea v. Babbitt*, 833 F.2d 196, 197-98 n.1 (9th Cir. 1987) (per curiam).

2. Washington Product Liability Act

The Washington Product Liability Act ("WPLA") "is the exclusive remedy for product liability claims." *Macias v. Saberhagen Holdings, Inc.*, 175 Wn. 2d 402, 409 (Wash. 2012). The

WPLA permits design defect claims if "the product was not reasonably safe as designed" and failure to warn claims if "adequate warnings or instructions were not provided." RCW 7.72.030(1). Washington has adopted the Restatement (Second) of Torts § 402A, which articulates the applicable standards. *Taylor v. Intuitive Surgical, Inc.*, 187 Wn. 2d 743, 760-61 (Wash. 2017) (citing Restatement (Second) of Torts § 402A (Am. Law. Inst. 1965)).

Comment k to section 402A "provides an exception to the application of strict liability for 'unavoidably unsafe products.'" *Taylor*, 187 Wn. 2d at 761. Under comment k, "where a product is inherently dangerous by nature but is still desirable because of its public benefit, it is an 'unavoidably unsafe product'" and "exempt . . . from strict liability under § 402A." *Id.* at 761-62. This is not a blanket exemption because "comment k specifies that the exception is not available to a manufacturer who fails to adequately warn." *Id.* at 762. Comment k provides that "[t]he seller of [unavoidably unsafe] products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use[.]"

3. Failure to Warn

To prevail on a failure to warn claim, a plaintiff must show that: (1) the defendant failed to sufficiently warn; (2) the plaintiff suffered damages; and (3) the defendant's failure to sufficiently warn of the dangers was a proximate cause of the plaintiff's damages. *See, e.g.*, *Breen*, 2021 WL 673485, at *5 (citing *Little v. PPG Industries, Inc.*, 19 Wn. App. 812, 818 (Wash. Ct. App. 1978)). On a failure to warn claim, "Washington courts apply the learned intermediary doctrine." *Sherman v. Pfizer, Inc.*, 8 Wash. App. 2d 686, 695 (Wash. Ct. App. 2019). "[U]nder the learned intermediary doctrine, the manufacturer satisfies its duty to warn the patient of the risks of its product where it properly warns the prescribing physician." *Taylor*, 187

Wash. 2d at 757. However, in addition to warning the physician, "the manufacturer has an independent duty to warn the purchaser of the product" such as, here, the hospital where Mr. Bosley's surgery was performed. *Id.* at 758; *see* Summ. J. Resp. at 23-24.

i. Adequate Warning

The Attune Device's packaging came with a warning of adverse events and complications, including "loosening" and "tibial subsidence[.]" (Second Pauley Decl. (dkt. # 74) at ¶ 8, Ex. F (dkt. # 74-6) at 8.) Defendants contend this warning was adequate as a matter of law. (Summ. J. Mot. at 10-11.) Dr. Barrett testified in his deposition that he was "well aware" of the loosening and tibial subsidence risks at the time he implanted the Attune Device in Mr. Bosley's leg. (Second Pauley Decl., Ex. A (Barrett Dep. (dkt. # 74-1) at 74:5-74:7).) Dr. Barrett's opinion is that loosening and tibial subsidence caused Mr. Bosley's implant failure. (*Id.* at 74:8-78:10.)

In determining whether a device's warnings are adequate as a matter of law, "[t]he court must examine the meaning and context of the language and the manner of expression to determine if the warning is accurate, clear and consistent and whether the warning portrays the risks involved[.]" *Est. of LaMontagne v. Bristol-Myers Squibb*, 127 Wn. App. 335, 344 (Wash. Ct. App. 2005). Here, the Court cannot conclude as a matter of law that the Attune Device's package insert warnings were adequate. While Dr. Barrett opines that the loosening warned of in the package insert caused the implant to fail, Dr. Bonutti opines that debonding of the implant from the cement was the cause.[4] (*See* First Pauley Decl., Ex. A at 4.) Because a genuine issue of

[4] Defendants maintain that "'debonding' is not synonymous with 'loosening.'" (Summ. J. Reply at 6.) Nonetheless, Dr. Barrett's deposition testimony indicates that surgeons may use the term "debonding" to mean separation either at the bone-cement interface or the cement-implant interface. (First Pauley Decl., Ex. B (Barrett Dep. at 12:16-19) ("[Y]ou can have debonding of the implant cement from the bone itself, or you can have debonding of the implant from the cement and the cement is still intact in the bone.").) This discrepancy further underscores that factual issues remain.

material fact remains as to whether the warnings encompassed the harm that Mr. Bosley suffered, Defendants are not entitled to summary judgment on this issue. *Cf. Est. of LaMontagne*, 127 Wn. App. at 350 (holding warning was sufficient where plaintiff "suffered the very injury that the package insert warned of").

ii. Proximate Cause

Because Defendants have not established as a matter of law that they provided an adequate warning, they have not established that they "properly warn[ed] the prescribing physician." *Taylor*, 187 Wash. 2d at 757. Accordingly, Defendants cannot establish entitlement to summary judgment based on the learned intermediary doctrine. Nevertheless, Defendants argue that Dr. Barrett was "actually and independently aware" of the risks of loosening and, therefore, did not rely on the Attune Device package warnings. (Summ. J. Mot. at 11-13.) Relatedly, Defendants argue that Dr. Barrett never read the insert, and testified that he did not use any implant other than the Attune Device without a specific reason, and therefore Mr. Bosley cannot establish that any inadequacy in the warnings proximately caused his harm.[5] (*Id.* at 13-14.)

Defendants' arguments misconstrue Dr. Barrett's testimony. Dr. Barrett testified he "never saw the package insert on the day [he] inserted [the Attune Device] into Mr. Bosley" but that he was "generally familiar with the content of the ATTUNE package insert[.]" (Second Pauley Decl., Ex. A (Barrett Dep. (dkt. # 74-1) at 66:8-66:22).) Dr. Barrett was aware of the risks described in the package insert, and there is no evidence that Dr. Barrett learned of these risks

[5] Defendants argue that Dr. Barrett still implants the Attune Device today. (Summ. J. Mot. at 14.) But Dr. Barrett's deposition testimony indicates he has used the Attune S+, the successor to the Attune Device, since it became available in 2017. (Second Pauley Decl., Ex. A (Barrett Dep. (dkt. # 74-1) at 200:22-201:7).)

from any source other than Defendants. That Dr. Barrett did not read the package insert on the day of Mr. Bosley's surgery does not mean he had not read it at any other time or learned of its contents.[6] Therefore, drawing all justifiable inferences in Mr. Bosley's favor, if Defendants had provided warnings of the risk of debonding from the cement, Dr. Barrett could have been made aware of those risks and may have made a different decision as to what device to implant.

Defendants cite *Breen*, where this Court held that, "[i]n order to prove causation, [plaintiff] must show that her implanting physician was aware of the alleged inadequate warning made by Defendants." *Breen*, 2021 WL 673485, at *5; *see* Summ. J. Mot. at 13. Here, Dr. Barrett testified that he was aware of Defendants' warning. (Second Pauley Decl., Ex. A (Barrett Dep. (dkt. # 74-1) at 66:8-66:22).) In *Breen*, the implanting physician "testified that he has never relied on written materials from [defendants]" but instead "relied on his training and education to inform him as to the risks and potential complications of the [device at issue]," and was aware that "the FDA had issued a public health notification" related to the device. 2021 WL 673485, at *1. Here, in contrast, Dr. Barrett acknowledged that he was aware of Defendants' warning, and did not indicate any other source of information. Applying the rule in *Breen* and drawing all reasonable inferences in favor of the nonmoving party, Mr. Bosley has presented evidence that Dr. Barrett "was aware of the alleged inadequate warning made by Defendants." *Breen*, 2021 WL 673485, at *5. Accordingly, Defendants are not entitled to summary judgment on this issue.

4. Design Defect

i. Permissible Claim

Defendants contend design defect claims are prohibited pursuant to comment k to section 402A of the Restatement (Second) of Torts, citing *Adams v. Synthes Spine Co, LP*.

[6] Defendants appear to acknowledge as much. (*See* Summ. J. Reply at 11 ("warnings were provided to Plaintiff's surgeon and . . . he knew of the stated risks").)

(Summ. J. Mot. at 15 (citing 298 F.3d 1114 (9th Cir. 2002)).) In *Adams*, the Ninth Circuit stated that "Washington law rules out strict liability for prescription medical products such as the [device at issue], provided that proper warning is given to the physician." 298 F.3d at 1118. *Adams* was a failure to warn case. The Ninth Circuit rejected plaintiff's theory that her implanting physician "wasn't adequately warned that [the device] could break" because the device's "instructions say that these implants can break" and, hence, there was not "any evidence in the record from which reasonable jurors could conclude that the warning was inadequate." *Id.* at 1116-18. The fact that implanting physicians typically did not remove the device, contrary to the manufacturer's recommendation, did not render the warning inadequate. *Id.* at 1118.

Here, Mr. Bosley alleges a distinct design defect claim: that the Attune Device's lack of rough surfacing and undercut pockets made implant-cement debonding more likely. (Second Am. Compl. at ¶¶ 1-2.) While Mr. Bosley also alleges a failure to warn claim, on the theory that Defendants should have warned of the increased risk of debonding, the two claims are distinct. (*Id.* at ¶¶ 134-44.)

Defendants also cite *Transue v. Aesthetech Corp.*, which included a heading stating: "Under Washington law, comment k affords a blanket exemption from strict liability for design defects in medical devices or products." (Summ. J. Mot. at 15 (citing 341 F.3d 911, 915 (9th Cir. 2003)).) In *Transue*, the Ninth Circuit made this statement in rejecting plaintiff's argument that not all prescription medical products were covered by comment k. 341 F.3d at 915-16. After determining that comment k applied to the device at issue, however, the Ninth Circuit held that "comment k should not be construed to provide protection for manufacturing defect claims based on unavoidably unsafe products." *Id.* at 917. As discussed above, the exception in comment k

only protects manufacturers from strict liability if products "are properly prepared and marketed, and proper warning is given[.]" Restatement (Second) of Torts, § 402A, comment k.

The Court concludes design defect claims for medical devices are not prohibited under Washington law. *See, e.g.*, *Payne v. Paugh*, 190 Wn. App. 383, 410 (2015) (medical device design defect claim tried to jury); Wash. Pattern Jury Instr. Civ. 110.02.01 ("A [pharmaceutical] [medical product] manufacturer has a duty to use reasonable care to design [drugs] [medical products] that are reasonably safe.").

ii. Elements of Claim

A plaintiff may establish design defect under the "risk utility test" by "showing that, at time of manufacture, the likelihood that the product would cause the plaintiff's harm or similar harms, and the seriousness of those harms, outweighed the manufacturer's burden to design a product that would have prevented those harms and any adverse effect a practical, feasible alternative would have on the product's usefulness." *Soproni v. Polygon Apartment Partners*, 137 Wn. 2d 319, 326 (Wash. 1999). "Alternatively, a plaintiff may employ the 'consumer expectations' test, which requires the plaintiff to show that the product was 'unsafe to an extent beyond that which would be contemplated by the ordinary consumer.'" *Id.* at 326-27 (quoting *Falk*, 113 Wn.2d at 654; RCW 7.72.030(3)).

Under the consumer expectations test, Defendants argue that testimony from Dr. Barrett and their Rule 30(b)(6) representative establishes that the Attune Device was equal or superior to contemporaneous devices. (Summ. J. Mot. at 17.) Dr. Barrett testified that "registry data" "showed that the ATTUNE was equal to or superior to current generation knee replacements" in terms of "survivorship in its knee patients[.]" (Second Pauley Decl., Ex. A (Barrett Dep. (dkt. # 74-1) at 25:20-26:4).) Liam Rowley, Defendants' Rule 30(b)(6) representative, testified that

the Attune Device "performs really well and has great satisfaction, as well as survivorship." (Ex. E (Rowley Dep. (dkt. # 74-5) at 41:12-14).)

Dr. Bonutti, however, testified that the "Sigma" device, available prior to the Attune Device, had undercut pockets and greater surface roughness that made it superior for preventing debonding at the implant-cement interface. (First Pauley Decl., Ex. A at 7-8.) A customer would not expect a less safe alternative to replace the Sigma. There is, accordingly, a genuine issue of material fact as to whether Mr. Bosley may establish a design defect under the consumer expectations test.

Under the risk utility test, Defendants argue that Mr. Bosley must prove the existence of an alternative design that was practical and feasible, and cannot rely on the Attune S+ because it was not in use at the time of Mr. Bosley's surgery. (Summ. J. Mot. at 18.) Mr. Bosley, however, relies on the "Sigma" implant, which was available before the Attune Device came on the market. (*See* Summ. J. Resp. at 2.) The Sigma device had the undercut pockets and greater surface roughness that Dr. Bonutti opined would have made the Attune Device safer. (First Pauley Decl., Ex. A at 7-8.) Accordingly, Defendants' argument fails.[7] The Court concludes Defendants are not entitled to summary judgment dismissing Mr. Bosley's design defect claim.

5. Mr. Bosley's Knowledge of Defect

Defendants contend Mr. Bosley's deposition testimony establishes that he researched problems with the Attune Device in 2013, before it was implanted in his left leg in 2014. (Summ. J. Mot. at 12.) Defendants contend that, therefore: (1) proximate cause cannot be established for the failure to warn claim because Mr. Bosley agreed to the surgery knowing of the problems; and (2) the three-year statute of limitations bars all of Mr. Bosley's claims.

[7] Defendants do not address Mr. Bosley's argument on reply, apparently conceding its merit.

Mr. Bosley contends Defendants have misinterpreted his deposition testimony and provides a declaration clarifying the testimony, stating that he performed his research after he encountered problems with his left knee implant. (Bosley Decl. (dkt. # 82) at ¶¶ 2-3.) Defendants argue Mr. Bosley's testimony was unambiguous and his declaration is a "sham affidavit" that should be disregarded. (Summ. J. Reply at 12-13.)

"The general rule in the Ninth Circuit is that a party cannot create an issue of fact by an affidavit contradicting his prior deposition testimony." *Kennedy v. Allied Mut. Ins. Co.*, 952 F.2d 262, 266 (9th Cir. 1991). This rule, however, "does not apply to every instance when a later affidavit contradicts deposition testimony." *Id.* at 267. An affidavit may be accepted—and preclude summary judgment—"if the affiant was confused at the deposition and the affidavit explains those aspects of the deposition testimony[.]" *Id.* at 266 (quoting *Miller v. A.H. Robins Co.*, 766 F.2d 1102, 1104 (7th Cir. 1985)). "Therefore, before [disregarding the affidavit], the district court must make a factual determination that the contradiction was actually a 'sham.'" *Id.* at 267.

Mr. Bosley testified that in 2013, one year before his left knee implant at issue in this case, he had an Attune Device implanted in his right leg. (Second Pauley Decl. at ¶ 4, Ex. B (Bosley Dep. (dkt. # 74-2) at 141:24-142:1).) Mr. Bosley testified that he researched problems with the Attune Device because it failed in his left knee much sooner than expected:

> Q: After you heard ATTUNE -- the word "ATTUNE" I guess, from Dr. Barrett and he described it, did you do any research on your own about ATTUNE?
>
> A: I would say I read up on problems that the ATTUNE system has caused. Umm–
>
> Q: And—I guess let me ask a better question and limit the time period. In between the time that you first heard the word "ATTUNE" from Dr. Barrett and the time that you had your left knee replacement surgery, did you perform any research on your own about ATTUNE?

A: That's how I found out about problems that ATTUNE—I looked it up myself to see that there were complications with it not holding up, because I was told that they usually last around 20 years or so. But my left knee implant, it come loose within four and a half years, so I was trying to find out what could have caused that to happen. I became very curious to what problems were they having with this system. I wanted to know. I wanted to know—

(*Id.* at 144:8-145:2.)

Mr. Bosley also requested medical records related to his 2014 left knee implant:

Q: Did you request records from Proliance Surgeons in relation to your 2014 left knee arthroplasty procedure?

A: I did that the third day after surgery.

. . .

Q: How soon after your initial 2013 right knee implant surgery did you request records from Proliance Surgeons?

A: As I recall, maybe the first week.

Q: So were you experiencing issues with that implant following the first week of that surgery?

A: No. That's what's so different. I've been successful, I think, with my right versus my left. My left has given me the dickens. So I don't guess there was anything done differently. They were both knee replacements initially, and—(Indiscernible crosstalk.)

(Second Pauley Decl., Ex. B (Bosley Dep. at 70:11-13, 70:19-71:3).) The deposing attorney attempted to clarify when Mr. Bosley requested records, noting the apparent contradiction between requesting records in 2013, prior to the left knee implant, and the motivation to request records arising due to problems with the left knee implant:

Q: And your testimony earlier was that you requested records shortly after your right knee total arthroplasty in 2013 and that you had requested records related to your knee surgeries because you had issues with that; is that right?

A: Yes.

> Q: And so my question is: If you didn't experience issues immediately following your right knee total arthroplasty, why did you request records so shortly after that procedure?
>
> A: I had problems shortly after with my left. I mean, same body, different mechanics. Different things was happening with my left than my right. I wanted to get on top of it in the event if there was something different, I'd try to understand it. Some things you don't get a chance to go back and redo, and knee surgeries are very extensive.

(*Id.* at 71:14-72:5.)

In his declaration, Mr. Bosley explains his deposition testimony as follows:

> I didn't mean that I had performed my research before I had my [left knee] implant surgery on August 13, 2014. I did my research after four and a half years of knee pain and then finding out from Jana Flener on January 23, 2019 that my left knee implant had come loose. I did the research before my March 19, 2019 revision surgery, which replaced my August 2014 implant with new parts.
>
> In the same way, when I said that I requested records from Proliance Surgeons in relation to my 2014 left knee arthroplasty procedure "the third day after surgery," I was referring to the 2019 revision surgery[.]

(Bosley Decl. at ¶¶ 2-3.)

As Mr. Bosley's declaration explains, it is plausible that a layperson such as Mr. Bosley would confuse "replacement" surgery with "revision" surgery, since revision surgery "replaced" an old implant with a new implant. (*See* Second Pauley Decl., Ex. B (Bosley Dep. at 144:17); Bosley Decl. at ¶ 2.) Moreover, Mr. Bosley's declaration helps to explain the deposition testimony that he became motivated to research Attune Device problems only after his own experience with the failed left knee implant.[8] (Second Pauley Decl., Ex. B (Bosley Dep. at 144:21-23) ("I looked it up . . . because I was told that they usually last around 20 years or so.

[8] The deposing attorney may have inadvertently introduced confusion by asking if Mr. Bosley requested medical records "in *relation to* your 2014 left knee [surgery]," which Mr. Bosley explains he did after the 2019 surgery to address the failure of his 2014 implant. (Second Pauley Decl., Ex. B (Bosley Dep. at 70:11-12) (emphasis added).) The attorney then switched to referring to the 2013 surgery. (*Id.* at 70:19-20 ("How soon after your initial 2013 right knee implant surgery did you request records. . ?").)

But my left knee implant, it come loose within four and a half years[.]").) Mr. Bosley's deposition testimony indicates that his research was motivated by the left knee implant failure, consistent with his declaration. (*Id.* at 70:25-71:1 ("My left has given me the dickens."), 71:24 ("I had problems shortly after with my left.").)

Because confusion is a reasonable explanation for the apparent discrepancies in Mr. Bosley's testimony, as explained by his declaration, the Court concludes there is insufficient evidence for a factual finding that Mr. Bosley's declaration is a sham. The declaration will not be disregarded. Accordingly, Defendants are not entitled to summary judgment on the basis that Mr. Bosley knew of problems with the Attune Device in 2013.

Because the Court concludes Defendants' Summary Judgment Motion should be denied, the Court need not reach Mr. Bosley's arguments concerning Dr. Barrett's status as a learned intermediary, spoliation of evidence, and Defendants' duty to warn the hospital. (Summ. J. Resp. at 2, 11, 14, 22-24.)

IV. CONCLUSION

For the foregoing reasons, the Court DENIES Defendants' Daubert Motion (dkt. # 65) and DENIES Defendants' Summary Judgment Motion (dkt. # 73).

Dated this 15th day of September, 2023.

MICHELLE L. PETERSON
United States Magistrate Judge